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PATENT APPLICATION
Docket No. 7678.350.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:		)
	Steven D. Jensen, et al.	)
Serial No.:	09/710,181	) Art Unit
		) 1616
Filed:	November 10, 2000	)
Conf. No.:	4245	)
For:	COMPOSITIONS AND METHODS FOR WHITENING AND DESENSITIZING TEETH	)
Examiner:	Alton Nathaniel Pryor	)
Customer No.:	022913	)

REPLY BRIEF

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Commissioner for Patents
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Dear Sir:

This Reply Brief is being timely submitted in the appeal within two months of the Examiner's Answer, which was mailed August 10, 2006.

The Examiner's Answer is noteworthy in that the Examiner conceded certain points argued by Appellants in their Appeal Brief. First, the Examiner removed the obviousness-type double patent rejection relative to U.S. Patent No. 6,309,625. Answer, p. 5. That means that the *claims* of the '625 patent do not reasonably teach or suggest a dental bleaching and desensitizing composition that includes a peroxide dental bleaching agent in an amount so as to have a tooth bleaching effect, a potassium nitrate desensitizing agent in a range of about 0.01% to about 2% by weight in order to reduce tooth sensitivity that may be caused by the peroxide bleaching agent, and a carrier. Second, the Examiner acknowledged that the teachings contained within the

specification of U.S. Patent No. 6,306,370, including the examples (more specifically Examples 7 and 14), cannot be relied on when rejecting the claims under obviousness-type double patenting. Answer, p. 7. Only the claims of the '370 patent are now being relied upon in maintaining the obviousness-type double patenting rejection.

Whereas the Examiner's Answer removed the double patenting rejection relative to the '625 patent, it did so on the grounds that "Appellant is correct in that the claims in USPN '625 make[] no suggestion to dental bleaching composition[s] comprising 0.5 to 50% peroxide." Answer, p. 5. The problem with this statement is that Appellants did not argue in their Appeal Brief that that appealed claims are patentable based on the concentration range of *peroxide*, but rather due to the surprising and unexpected results that are obtained when utilizing an amount of potassium nitrate within the narrowly claimed range of about 0.01% to about 2% by weight.

More particularly, Appellants argued the counterintuitive and unexpected finding in a comparative study that utilizing a relatively small amount of potassium nitrate (*i.e.*, 0.5%) works better in counteracting tooth sensitivity caused by a peroxide bleaching agent than a larger amount (*i.e.*, 3%). Appellants also cited *In re Kollman*, 595 F.2d 48, 56 (CCPA 1979), and argued that a trend was shown that permits the evidence of unexpected results to apply to the entire range of about 0.01% to about 2% potassium nitrate rather than the single point of 0.5%. Whereas previous office actions argued that the single point of 0.5% potassium nitrate used in the study could not support the claimed range of about 0.01-2%, subsequent office actions acknowledged that the evidence of unexpected results applied to the range, not just the point, based on the trend that could be extrapolated from three data points tested: 0%, 0.5% and 3% potassium nitrate.

In short, both the Examiner's Answer and the April 5, 2005 office action acknowledge that the data showing unexpected results for the narrow range of potassium nitrate is persuasive to rebut a *prima facie* rejection of the claimed range of potassium nitrate over the ranges recited in the '625 and '370 patents. However, both the Examiner's Answer and the April 5, 2005 argue that the data of unexpected results do not support the claimed range of bleaching agent, which is about 0.5-50% by weight. Based on this, the Examiner appears to take two largely inconsistent positions: (1) the evidence is persuasive relative to the potassium nitrate range and (2) the evidence is unpersuasive because it does not apply to the entire peroxide range. Appellants respond by reiterating that the purpose of the study was to identify the amount of *potassium nitrate* that works best in reducing tooth sensitivity caused by the peroxide, not the amount of

peroxide that might cause more or less sensitivity. Because the appealed claims are commensurate in scope with the result-effective variable that was the subject of the study, Appellants believe the claims are correctly worded so as to distinguish over the *claims* of the '625 and '370 patents. Indeed, while the potassium nitrate range recited in the appealed claims was initially found to be *prima facie* obvious over the claims of the '625 and '370 patents, the Examiner later acknowledged that the evidence showing unexpected results for the claimed potassium nitrate range was "convincing". *See* Answer, p. 7. Thus, the Examiner admitted that the claims of the '625 and '370 patents do not teach or suggest the potassium nitrate range. It is for this reason the Examiner attempts to change the focus from the potassium nitrate range to what is alleged to be the "claimed range of peroxide". Answer, p. 7.

The claims do not, however, recite a peroxide range. Instead, they recite a range for the "dental bleaching agent" which, in turn, "compris[es] at least one peroxide". It is well-known that different bleaching agents having greatly varying peroxide contents. For example, carbamide peroxide, the bleaching agent used in the comparative study, is a complex of hydrogen peroxide and urea. It has an effective hydrogen peroxide concentration of about 30%. Molecular hydrogen peroxide, on the other hand, contains 100% hydrogen peroxide. Thus, a composition that included 10% carbamide peroxide (one of the tested values in the comparative study) would have the same hydrogen peroxide content as one that included only about 3% molecular hydrogen peroxide. At the other end of the spectrum, a composition that included a hypothetical bleaching agent having a peroxide content of only 10% would need to include 45% of the hypothetical bleaching agent to impart the same level of peroxide as a composition that included 15% carbamide peroxide (one of the tested values in the comparative study). Thus, the seemingly broad range of about 0.5-50% is not nearly so broad as the Examiner would have it. The range merely accounts for the greatly varying amounts of peroxide provided by commonly-known dental bleaching agents.

By way of example, let's assume for the sake of argument that the appealed claims were limited to compositions having a dental bleaching agent in a range of 10-15%. Such claims would exclude a composition that included 3% molecular hydrogen peroxide even though the amount of peroxide provided by 3% molecular hydrogen peroxide is approximately the same as that provided by 10% carbamide peroxide, an amount that was employed in the comparative study. Such claims would also exclude a composition that included 45% of a hypothetical bleaching agent that only provided 10% hydrogen peroxide, even though it provided the same

level of peroxide as 15% carbamide peroxide, an amount that was employed in the comparative study. This succinctly illustrates that reciting a hypothetical dental bleaching agent range of 3-45% is arguably equivalent to claiming 10-15% carbamide peroxide when taking into account the varying amounts of hydrogen peroxide provided by only two other types of dental bleaching agent.

Moreover, *In re Kollman*, *supra*, held that a relatively small number of data points can support a broader range if a trend can be discerned. In the comparative study, increasing the carbamide peroxide content from 10% to 15% had no significant effect on tooth sensitivity. *See* Fischer Declaration, ¶¶ 12 and 13. That shows a trend in which tooth sensitivity remains constant over a range of different levels of bleaching agent, all things being equal. Based on the fact that there was little or no change in tooth sensitivity regardless of whether the carbamide peroxide content was 10% or 15%, one may reasonably extrapolate the results of the comparative study for carbamide peroxide contents lower than 10% and greater than 15%. It would be unreasonable to assume that the sensitivity results only apply to compositions that include exactly 10% or 15% carbamide peroxide. Thus, the claims need not be limited to a range of carbamide peroxide of 10-15%. Higher or lower amounts than this range would be reasonably supported by the comparative study. Because a claim for 10-15% carbamide peroxide supports a claim for 3-45% of a generic "dental bleaching agent" to account for bleaching agents that provide higher or lower quantities of peroxide, but because the claims need not be limited to 10-15% carbamide peroxide, it follows that the claims need not be limited to 3-45% of a generic dental bleaching agent. Even broader ranges would be permissible so long as the amount of dental bleaching agent was sufficient to "have a tooth bleaching effect" as also recited in the claims. In short, the claimed range of 0.5-50% dental bleaching agent is not overly broad but consistent with the comparative study given the fact that (1) no significant change in tooth sensitivity was observed by varying the carbamide peroxide content from 10% to 15% and (2) the peroxide content of known dental bleaching agents can greatly vary one from another, which supports a relatively broad range to account for such variability.

In any event, focusing solely on the dental bleaching agent range ignores another important limitation in the claims that further narrows their scope. In addition to the claimed bleaching agent range of about 0.5-50%, the claims also require an amount of bleaching agent that is able to "have a tooth bleaching effect". Thus, a composition that included 0.5% of a dental bleaching agent would not infringe the claims unless the dental bleaching agent also

provided "a tooth bleaching effect". In other words, it is improper to focus solely on the range without considering the additional modifier that the dental bleaching agent must also "have a tooth bleaching effect". Unless tooth bleaching occurs, the likelihood of tooth sensitivity is diminished. For this reason, the claims were narrowed to ensure a quantity of bleaching agent so as to "have a tooth bleaching effect" notwithstanding the range. This further renders the claims consistent with the results of the comparative study, which studied the effect on tooth sensitivity when including an amount of carbamide peroxide that bleached teeth coupled with an amount of potassium nitrate that offset tooth sensitivity caused by the carbamide peroxide.

Finally, the appealed claims do not, in fact, require any particular amount of dental bleaching agent, only that the amount fall somewhere within the range of about 0.5-50%. It is not as if the claims actually require 0.5% or 50% dental bleaching agent. Had the claims recited *no* concentration range for the dental bleaching agent there would likely be no issue. No rejection was raised relative to the amount of the carrier even though no range was recited. Because it is likely that claims specifying no particular amount of dental bleaching agent would be allowed over the claims of the '625 and '370 patents, and because including a range cannot be understood as somehow broadening the claims, it logically follows that the appealed claims are patentable over the claims of the '625 and '370 patents notwithstanding the range. That is particularly true in view of the further limitation that the dental bleaching agent must be included in an amount so as to "have a tooth bleaching effect".

In conclusion, Appellants submit that the appealed claims are patentable over the claims of the '625 and '370 patents. The comparative study shows and "the Examiner agrees that [the] results [of the study] are convincing as well as unexpected". *See* Answer, p. 7. The concentration range for the dental bleaching agent is a red herring that was raised in an attempt to divert attention from the comparative study and the actual language of the claims, which are consistent and commensurate in scope with the comparative study.

Dated this 1st day of September 2006.

Respectfully submitted,

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